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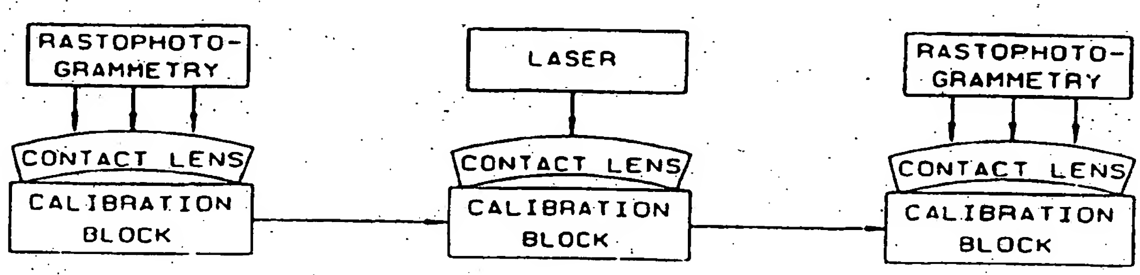

(57) Abstract

A method of using rastophotogrammetry and Placido-disc videokeratoscopy in ophthalmological surgery to calibrate a surgical laser wherein the effect of laser ablation on various substrates is measured by performing rastophotogrammetry or Placido-disc videokeratoscopy on the substrate before and after laser ablation to determine whether there is a uniform ablation and no unwanted effects created by the laser. The substrate can be calibration block, an intraocular lens implant, a contact lens, an artificial cornea, or cornea.

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METHOD OF EVALUATING A LASER USED IN OPHTHALMOLOGICAL SURGERY

Technical Field

This invention relates to a method of using rastophotogrammetry and Placido-disc video keratoscopy in ophthalmological surgery, more specifically, to a method of using rastophotogrammetry, and Placido-disc video keratoscopy to evaluate and calibrate a laser used in refractive surgery so as to measure the amount of unwanted lens effect delivered by an excimer laser or other ultraviolet or infrared laser beams.

Rastophotogrammetry has been used in ophthalmological surgery to measure the surface contour or the optic nerve head and to measure corneal surface curvatures. In the technique of rastophotogrammetry a series of parallel lines or a grid is projected on the surface to be measured. Computerized digital analysis of a video image is performed to detect elevations or depressions of the surface being measured. Rastostereographic imaging is combined with image processing computer software to produce a model of the topography of the cornea, for example. Prior art uses of the technique have been limited to measuring epithelialized corneal surfaces, before and after refractive procedures such as radialkeratotomy and excimer photo-refractive keratectomy. Although useful, prior art applications of the technique only measure epithelialized corneal topography before and after surgical intervention. There is no predictive value in this technique, that is, the rastophotogram only measures changes in the corneal topography retrospectively. If the laser used during surgery is not properly calibrated, the laser

may have unwanted lens effect by removing corneal tissue in an uneven pattern leaving depressions (hot spots) or elevations (cold spots). The goal of the surgery is to perform a uniform ablation with a uniform laser beam, i.e., a laser beam having no unwanted lens effect. Furthermore, the prior art uses of rastophotogrammetry do not measure topographical changes in optic implants or on contact lenses.

Recently it has been determined that Placido-disc videokeratoscopy can be used to determine surface contour, particularly to visualize and determine the surface contour of a "Contact lens" or artifical cornea. The Placido-disc video keratoscope is a type of computerized videokeratography now available to ophthalmological surgeons. The instrument allows the surgeon to measure and modify corneal curvature. The basic videokeratograph instrument includes a light source projected onto the cornea. The modifications of the light by the corena is captured by a video camera and the information is analyzed by computer software. The data is displayed in a variety of formats including photographs and on a screen.

The Placido-disc imaging is an extension of the single mirror used in the keratometer. A series of rings is projected onto the cornea, and the reflected images are detected by a video camera. Curvature data is derived from the measured distances between the rings. The patient is placed before a corneascope projecting a 16-ring conical Placio-disc. The scope is positioned in front of the cornea. The instrument contains a video camera for image capture. The computer digitizes or converts the data obtained from the video output into a form that can be

analyzed. A number of highly sophisticated programs convert the data into a series of color graphics displays. Hard copies can be obtained from a color printer or a camera. The color graphics provide topographic maps. Systems currently commercially available include the EyeSys Corneal Analysis System (CAS) (EyeSys Laboratories) and the Topographic Modeling System (TMS) (Computed Anatomy, Inc.) Although Placido-disc vidoekeratoscopy systems work poorly on deepithelialized cornea after radial keratotomy, they can be used to evaluate the effect of laser ablation on an artifical cornea.

Excimer laser photorefractive keratectomy (PRK) has some inherent limitations that make pre-treatment PRK calibration mandatory. For example, optic degradation in the delivery system can lead to a spotty deterioraion of UV wavelength transmission (See Fig. 6), resulting in hot spots and cold spots. Misalignment of optics can induce unwanted astigmatism. Axis alignment for correction of astigmatism error must be precise. Furthermore, as the gas is expended during lasing, the power output deteriorates.

Generally, calibration systems for excimer laser PRK machines have been inadequate. Most manufacturers recommend ablation of polymethylmethacrylate test blocks. These blocks then are visually inspected for gross irregularities and the targeted dioptric correction is confirmed on a lensometer.

There are many problems associated with the lensometer as a calibration tool for PRK. First, the lensometer does not assess homogeneity of the ablation. Second, it is difficult to read the "ghost

image" (Fig. 12) used to define the endpoint. Third, the higher dioptric corrections become increasingly difficult to read. Fourth, multizone treatment regimens cannot be dissected and further complicate the determination of the endpoint. Finally, some machines have rough, irregular ablation surfaces that preclude the use of a lensometer for calibration (Fig. 13).

Background Art

It is, therefore, an object of the method of the present invention to use rastophotgrammetry to evaluate a surgical laser to prevent unwanted lens effect.

It is another object of the present invention to provide a method of using Placid-disc videokeratoscopy to evaluate a surgical laser.

Yet another object of the present invention is to provide a method of using rastophotogrammetry of Placido-disc videokeratoscopy before and after a laser ablation to confirm a uniform laser beam.

Still another object of the present invention is to provide a method of confirming the desired lens effect of the laser beam on a calibration block.

Yet another object of the present invention is to provide a method of quantifying the change in optic curvature of an intraocular lens imlant before and after laser treatment to alter the refractive power.

It is another object of the present invention to provide a method of using Placid-disc video keratoscopy to evaluate a surgical laser.

Still another object of the present invention is to provide a method of evaluating a laser using an artificial cornea of a known dioptric power employing

Placido-disc keratoscopy to measure the curvature of the artificial cornea to determine the effect of the laser beam on the artificial cornea.

Yet another object of the present invention is to provide a method of performing ophthalmological surgery in which a rastophotogrammetry is performed on a deepithelialized cornea so as to measure the topography of the deepithelialized cornea before and after laser ablation of the cornea.

It is another object of the present invention to overcome the problems associated with using a lensometer as a calibration tool for photorefractive keratectomy.

It is still another object of the invention to provide a method for using polymethylmethacrylate (PMMA) artifical corneas and commercially available topography instruments to provide quantitative information on laser ablation.

Briefly stated, a method of evaluating an eye surgery laser is provided wherein the effect of the laser ablation on various substrates is measured by performing rastophotogrammetry or Placido-disc videokeratoscopy on the substrate before, during, and after laser ablation to determine whether there is a uniform ablation and no unwanted effect. The substrate can be a calibration block, and intraocular lens implant, a contact lens, an artificial cornea or a human cornea.

<u>Brief Description of the Drawing</u>

Fig. 1 is a diagram illustrating the use of rastophotgrammetry to determine unwanted lens effect (i.e., hot or cold spots) of a laser beam;

Fig. 2 is a diagram demonstrating the use of

rastophotogrammetry to confirm the desired lens effect of a laser beam;

Fig. 3 is a diagram ilustrating the use of rastophotogrammetry in an ophthalmological surgical procedure;

Fig. 4A is a diagram illustrating the use of rastophotogrammetry to evaluate a laser based on the effect on a contact lens of a known refractive powwer;

Fig. 4B is a diagram illustraing the use of Placido-disc videokeratoscopy to evaluate a laser base on the effect on an artificial cornea of a kown refractive power;

Fig. 5 is a diagram illustrating the use of rastophotogrammetry to change the refractive index of an intraocular implant;

Fig. 5A is a diagram illustrating use of rastostereophotogrammetry to evaluate the effect of a laser on an artificial cornea of a known refractive power;

Fig. 6 is a UV transmission from an excimer laser showing spotty transmission due to optic degradation;

Fig. 7 is a PMMA test ablation showing irregularities in the surface;

Fig. 8 is a pre-ablation videokertoscope image of artifical cornea;

Fig. 9 illustrates post-ablation appearance of artifical cornea;

Fig. 10 are difference maps illustrating the quantitative effects of laser ablation of artifical cornea;

Fig. 11 are maps illustrating pre-ablation topography (left), post-ablation topography (right) and quantitative effects of laser ablation (bottom);

Fig. 12 illustrates a lensometer ghost image endpoint in a PMMA flat block;

Fig. 13 illustrates an irregular ablation surface;

Fig. 14 are rastosterographic images of pre-ablation PMMA cornea without a fluorescein dye;

Fig. 15 are topographies of manufacturer's calibration sphere before (left) and after (right) application of proprietary coating and a difference map (bottom); and

Fig. 16 is a calibration cornea (PMMA) imaged using a polarizing filter.

Best Mode for Carrying Out the Invention

As illustrated in Fig. 1, rastophotogrammetry is used to determine theamount of unwanted lens effect delivered by an excimer or other ultraviolet or infrared laser beam.

Rastophotogrammetry device used is as the type marketed by PAR Technology Corporation, Hartford, NY 13413. A calibration block, typically made of polymethylmethacrhrylate, is employed. The rastophotogrammetry is used before calibration to evaluate the laser beam. A rastophotogram is made of the calibration block, the laser is applied to the calibration block, and a rastophotogram is performed to see if the laser effect is a uniform ablation with no depressions (hot spots) or elevations (cold spots). As illustrated in Fig. 1, the rastophotogram confirms a uniform ablation of the calibration block.

Confirmation of a desired lens effect is illustrated in Fig. 2. A rastophotogram is made of the calibration block, the laser beam is applied to the calibration block, and a second rastophotgram is performed to confirm the desired lens effect in the

calibration block. For example, the desired lens effect is 4,000 dioptric, the amount of calibration block material that is removed at each point along the radius of the calibration block can be computed and the actual amount removed compared quantitatively and qualitatively to the effect desired. Moreoer, the astigmatic and multi-zone (asphersity) correction desired can be calibrated and measured quantitatively.

Fig. 3 illustrates the use of rastophotogrammetry in corneal surgery performed to alter the refractive index of the human cornea. As illustrated, a rastophotogram is made of a calibration block. As previously stated, the laser is applied to the calibration block to determine the amount of albation and to determine whether or not there is unwanted lens effect. In this manner and through these steps, it can be evaluated whether the laser is properly calibrated before the laser is used on the human eye. Next, a rastophotogram is performed on a deepithelialized human cornea. The laser is then applied to the deepithelialized cornea and ablation performed. Finally, a rastophotogrammetry is performed to determine if the proper refractive index of the deepithelialized cornea has been achieved. The steps may be repeated to validate repeated ablations.

As illustrated in Fig. 3, under-correction can be avoided by continuing the treatment session until the desired amount of correction is achieved. Furthermore, in order to enhance the quality of the video image at this point, a surface dye can be applied to the deepithelialized cornea. In addition, the rastophotogrammetry grid can be projected using various wave lengths and filters for optimal visualization of the projected grid. As shown in Fig.

15, a polarizing filter can be used to capture the image without the use of dye in the rastophotogram technique.

Fig. 4A illustrates the use of the rastophotogrammetry in the evaluation of the surgical laser using a contact lens of a known dioptric power. A contact lens of a known dioptric power formed from polymethylmethachrylate is fastened to a holding block, such as previously described polymethylmethachrylate calibration block. The contact lens can be constructed as an artificial cornea and can be white to facilitate imaging with the rastophotogrammetric system. Next, rastophotogrammetry is performed on the contact lens front surface to get an accurate baseline reading of the topography of the front suface of the lens. Next, the laser is used on the front curvature of the lens. Finally, a second rastophotogram is peformed to determine that the effect of the laser on the lens responds to the desired changed in the known dioptric power of the lens so that the laser can then be properly calibrated based upon the evaluation of the effect of the laser beam on the lens with known dioptric power. The steps in the procedure may be repeated to validate the calibration.

Fig. 4B illustrates the use of Placido-disc videokeratoscopy in the evaluation of a surgical laser using an artificial cornea of a known dioptric power. An artificial cornea of a known dioptric formed from polymethylmethachrylate or other appropriate material is fastened to a holding block, as previously described. The artificial cornea can be black plastic to facilitate imaging with a videokeratoscope. The artificial cornea should be colored all the way

through to that ablation does not penetrate the colored layer only.

Next, a Placido-disc videokeratoscope procedure is performed on the artificial cornea front surface to get an accurate baseline reading of the topography of the front surface of the cornea. A first videokertograph of the topography is made. Next, a laser is uded on the present curvature of the artifical cornea. A nonviscous, fine hydrophobic lubricant, such as a thin oil, can be placed on the ablated surface of the artificial cornea to enhance visualization since the ablated surface loses its reflectively. A second Placido-disc keratoscopy procedure is performed and a second videokeratograph is made. The first and second videokeratographs are compared to evaluate the ablating power of the laser. It will be appreciated by those skilled in the art that Placido-disc video keratoscope procedures work poorly on deepithelialized cornea right after surgery. However, the procedure works well for imaging the artificial cornea before and after ablation, as first described. Therefore, the Placido-disc keratoscopy can be used in connection with rastophotogrammetry in the surfical setting. The effect of the laser on an artificial cornea can be determined by the use of Placido-disc video keratoscopy. The laser is used to perform corneal ablation. Subsequently, rastophotogrammetry is performed on the deepithelialized cornea to determine corneal topography. Corneal ablation is performed and a repeat rastophotogram is made and compared to the first to validate the laser action.

Fig. 5 illustrates the use of the rastophotogram to determine the effective laser

adjustment of refractive index of an intraocular implant. As illustrated, the rastophotogrammetry procedure is performed on the intraocular implant as to determine a base line. Next, the laser beam is applied to the intraocular lens implant to alter the curavature of the implant and thereby alter the refractive power. The second rastophotogram of the intraocular implant is then performed to provide feedback mechanism to ascertain if the desired refractive change has been achieved. The procedure may be repeated until the desired change in refractive power is achieved.

It should be noted that laser holography (Eye Technology) can be used for topographical analysis, as well as videokeratoscopic techniques and rastostereography.

I have used propriety artificial corneas to provide high quality images for Placido-disc video keratoscopes and for a rastophotogrammetric topography machine. I tested an EyeSys System (Houston, Texas) as an example of a Placido-disc machine and the PAR Topography (New Hartford), New York) as an example of the rastophotogrammetric technology. I captured and analyzed images before and after an ablation with a VISX 20/20 excimer laser. Difference maps were utilized to calculate the net effects of the ablation.

The pre-ablation plastic corneas provided high quality images, as shown in Fig. 8. As shown in Fig. 9, post-ablation, the ablated portion lacked sufficient reflectivity to capture an adequate image for videokeratoscopic tests. I used a non-viscous coating to provide adequate reflectivity, taking care to avoid pooling. Such a coating is a synthetic aliphatic hydrocarbon with viscosity of 100°, cst of

1.8 using the ASTM D-455 test method, having a specific gravity of 0.797. Rastophotogrammetric images were obtained without a fluorescein dye or a reflective coating (Fig. 14). The difference maps, Figs. 10 and 11, provided quantitative information on the dioptric correction as well as information on the homogenicity of the ablation, size of the zone of full dioptric correction, and size of the transitional zones. No examples of central islands were identified. Astigmatic corrections provided information on the precise axis of the cylindrical correction and the magnitude of correction.

I assessed the potential for artifact induced by the propriety coating by confirming that the coating did not affect the topography machine's calibration surfaces (Fig. 16). Reproducibility was confirmed by multiple sequential applications of the coating to an ablated surface.

It should be noted that the ablation rate (surface layer depth removed per pulse expressed as microns per pulse) in PMMA is about 1.8 to 3.5 times less that in human corneal tissue. For any given laser system, the Plastic To Cornea (PTC) conversion factor (i.e., 1.8 to 3.5) is constant for PMMA to cornea. Nevertheless, the ablation rate in PMMA, and hence in cornea, varies depending upon several factors including fluence (i.e. power density expressed in millijoules (mj) per centimeter squared (cm^2). Fluence can vary at least 5 to 8%, pulse to pulse, in the range of 120 to 200 mj/cm^{-2}. Variable fluence and other factors, such as optic degradation, mean that calibration on PMMA before photorefractive keratectomy (PRK) is mandatory. For example, if the fluence is running high, then the PMMA ablation that

is programmed for a -4 might read -4.5 on rastophotogrammetry and videokeratoscopic topographic machines. In this case, the surgeon enters in the laser's computer the resultant dioptric corecion of -4.5 and the laser is programmed automatically to figure that 4.50/4.00 = 9/8 the amount of material is ablated per pulse, as originally targeted. Ablation on PMMA is repeated using 1/8 fewer pulses until the programmed (targeted) dioptric correction equals the realized (as measured by topography) correction in PMMA. Based upon the PTC factor of the particular laser system being used, (typically 1.8 to 3.5) the corneal ablation rate (material thickness per pulse) is calculated by multiplying the PMMA ablation depth per pulse by 1.8 to 3.5. For example, with the VISX system, the PMMA ablation rate (microns per pulse) is multiplied by 1.8 to get the ablation rate for the cornea. For LaserSight MiniExcimer, for example, the ablation rate in PMMA is multiplied by 3.4 to the ablation rate in the cornea.

Fig. 5A illustrates the use of the rastostereophotogrammetry, in addition to rastophotogrammetry, in the evaluation of a surgical laser using an artificial cornea of a known dioptric power. An artificial cornea of a known dioptric power formed from polymethylmethacrylate or other appropriate materials is fastened to a holding block, as shown. The artificial cornea can be of white plastic or fluorescin-impregnated plastic to facilitate the imaging with the laser. The artificial cornea should be colored or fluorescin-impregnated all the way through so that ablation does not penetrate the colored or fluorescin-impregnated layer only.

Following this, the rastostereophotogrammetry

procedure is performed on the artifical cornea front surface to get an accurate base line reading of the topography of the front surface of the cornea. A first rastostereophotogrammetry of the topography is made. Next, a laser is used on the present curvature of the artificial cornea. A second rastophotogrammetry procedure is performed and a second image is made. The first and the second images are compared to evaluate the ablating power of the laser. This procedure works well for imaging the artificial cornea before and after ablation, as initially described. Therefore, rastophotogrammetry is useful in this type of surgical setting. The effect of the laser on an artificial cornea can be determined by the use of rastophotogrammetry. The laser is used to perform corneal ablation. Subsequently, the rastophotogrammetry is performed on the deephithelialized cornea to determine corneal topography. Corneal ablation is performed and a repeat rastophotogram is made and compared to the first to validate the laser action. Once again, the purpose of this procedure is to attain the desired change in the refractive power of the cornea.

It will be appreciated that the laser also can be used to ablate an intraocular implant. The ablation rate inside the eye will have a plastic-implant conversion factor (PIC factor) depending upon the type of laser system. Nevertheless, the ablation rate in PMMA can vary, so pretreatment determinations are mandatory.

Various changes and modifications can be made in the foregoing description and drawings within the scope of the present invention. Therefore, the foregoing description and accompanyging drawingas are

to be interpreted as illustrative and not in a limiting sense.

WHAT IS CLAIMED IS:

1. A method of evaluating and programming a surgical laser used in ophthalmological surgery comprising the steps of:

determining a first topography of an artificial cornea;

applying a laser beam to the artificial cornea;

performing an ablation on the artificial cornea with the laser beam;

determining a second topography of the artificial cornea after performing the test ablation;

comparing the second topography to the first topography;

evaluating an ablating effect of the surgical laser based upon the comparison; and

programming the laser to produce a desired ablating laser beam based upon the evaluation.

2. The method of claim 1 wherein the steps of determining a first and a second topography further include performing a rastophotogrammetric procedure.

3. The method of claim 1 wherein the steps of determining a first and a second topography further include performing a videokeratoscopic procedure.

4. The method of claim 1 wherein the steps of determining a first and a second topography further include performing a laser holographic procedure.

5. The method of claim 1 wherein said step of programming the surgical laser further includes programming the laser using a predetermined dioptric number.

6. The method of claim 1 wherein the step of determining a first and a second topography further

includes a laser holographic procedure.

7. The method of claim 1 wherein said test substrate is a PMMA block.

8. The method of claim 1 wherein the step of programming the surgical laser further includes programming the laser using a plastic to cornea conversion factor ranging from 1.8 to 3. 5 dioptric number.

9. A method of evaluating surgical laser for use in ophthalmological surgery comprising the steps of:

performing a first rastostereophotogrammetry procedure on a substrate to determine surface contour of said substrate;

making a first rastostereophotogram;

applying a laser beam to said substrate;

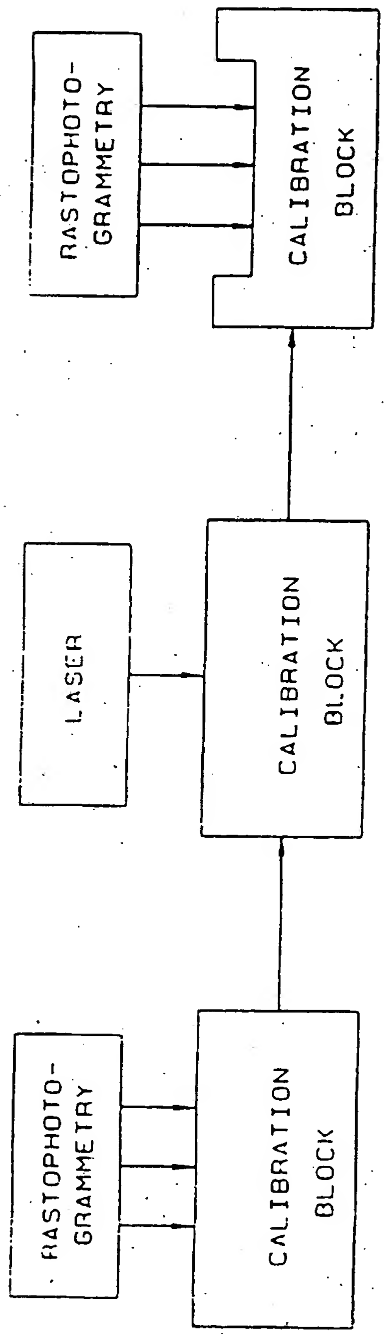
abalting said substrate with said laser beam;

performing a second rastostereophotogrammetry procedure on said substrate to determine a second surface contour of said substrate after ablation;

making a second rastostereophotogram; and

evaluating said laser beam performance based upon a comparison of said second and said first rastostereophotogram.

10. The method of claim 9 wherein said step of performing a first rastostereogrammetry procedure on a substrate to determine surface contour of said substrate further includes performing a first rastostereogrammetry procedure on an artificial cornea of known dioptric power.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CALIBRATION
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GRAMMETRY
CALIBRATION
BLOCK

FIG. 1

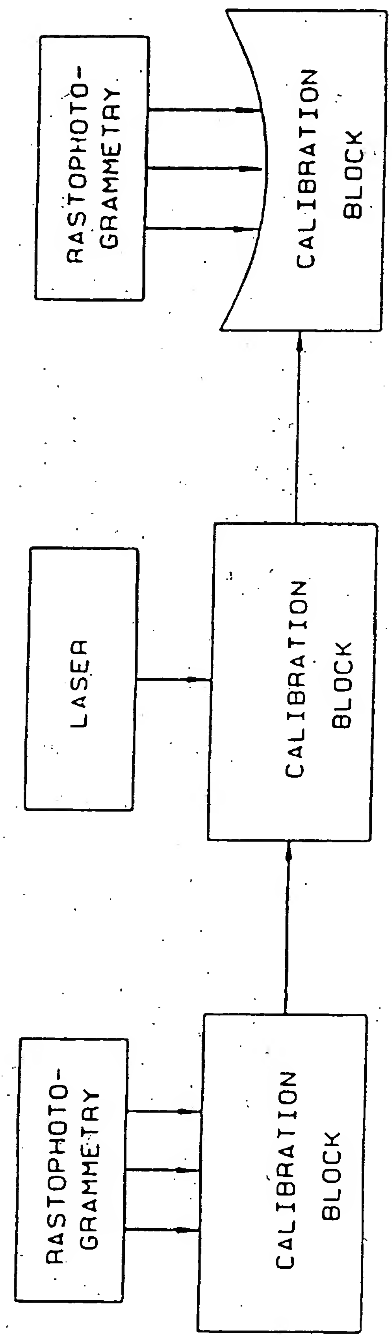
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FIG. 2

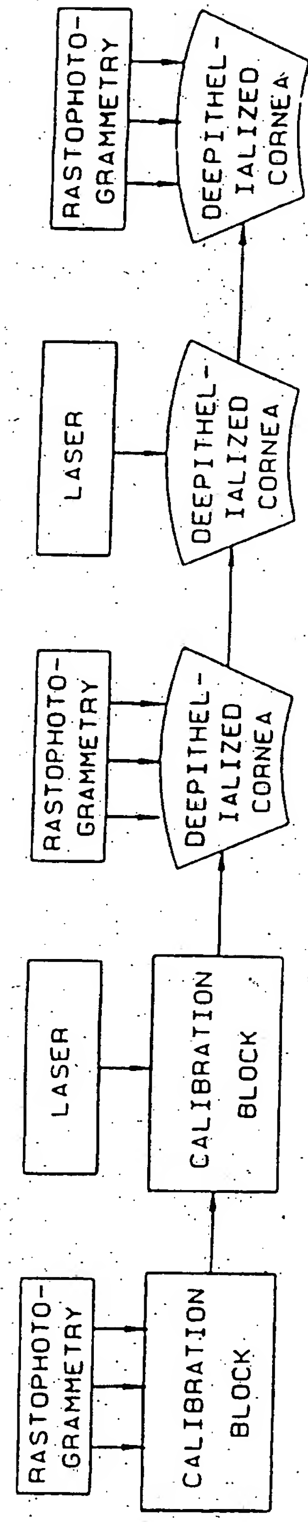
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FIG. 3

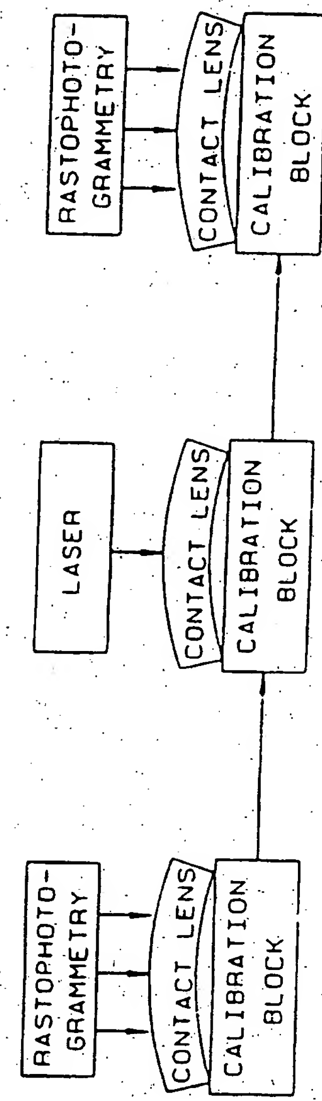
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FIG. 4A

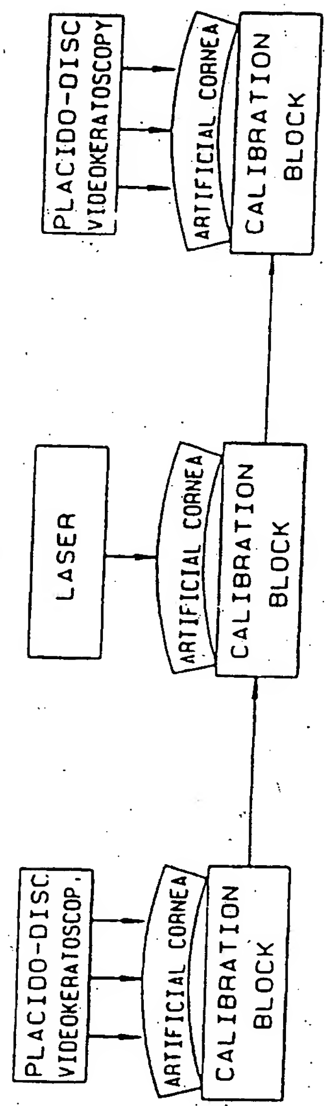
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FIG. 4B

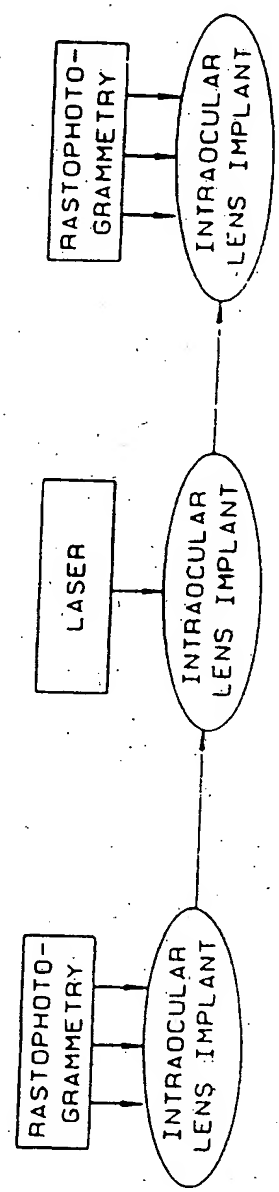
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FIG. 5

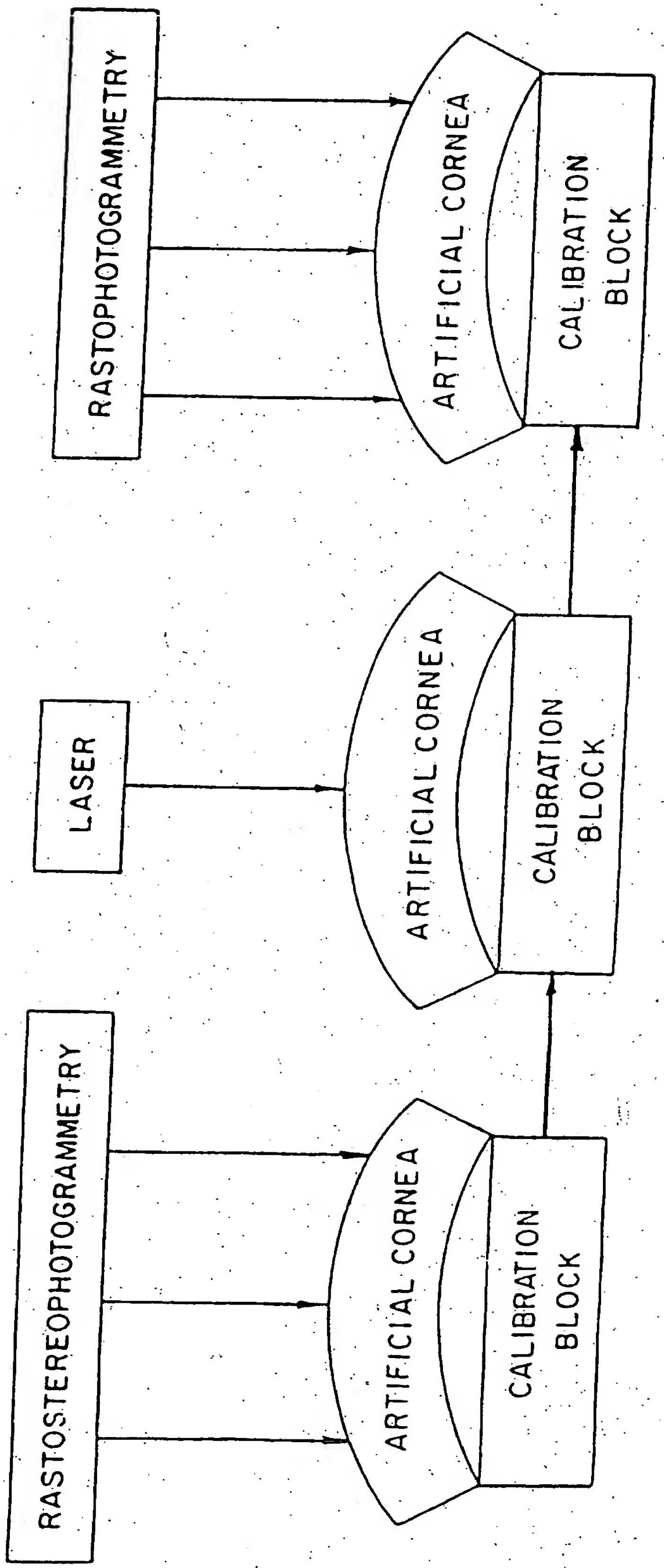
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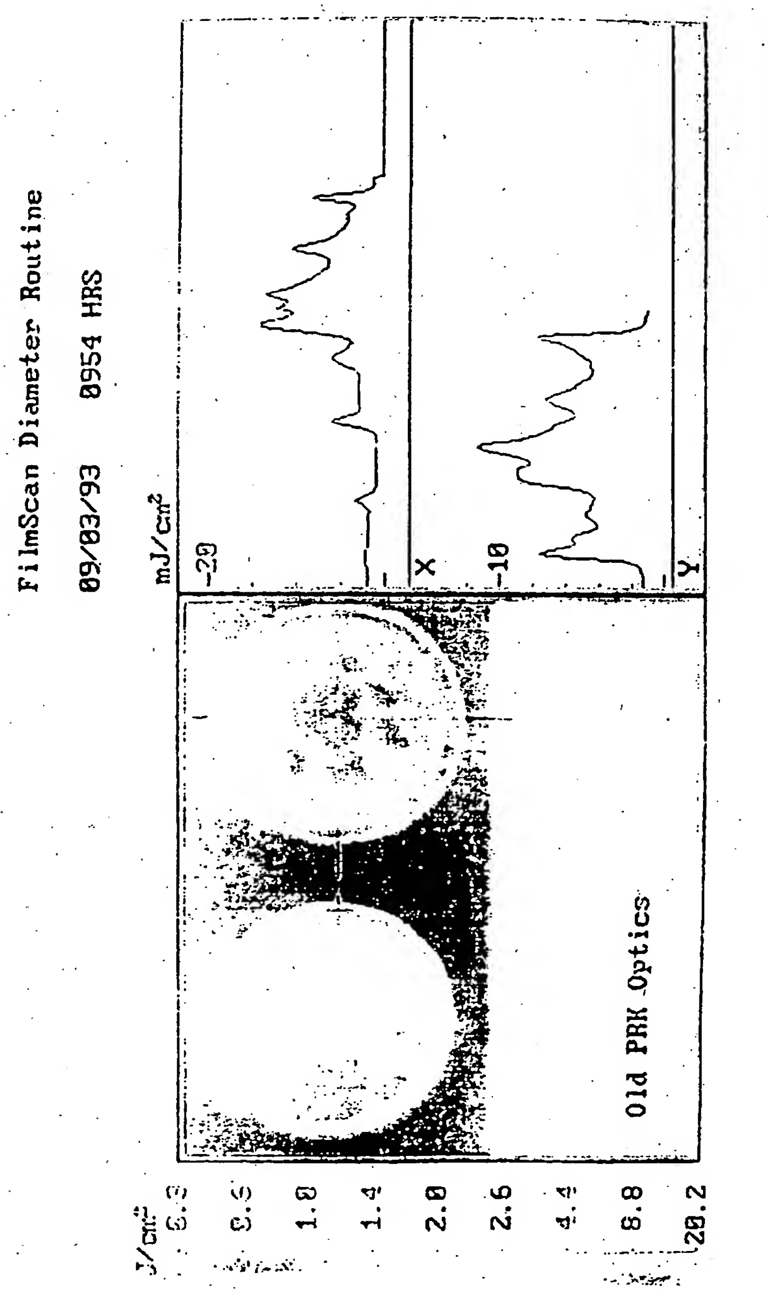
FIG. 5A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mJ/cm²
-20
X
-10
Y
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J/cm²
1.0
1.4
2.0
2.6
4.4
8.8
20.2

FIG.6

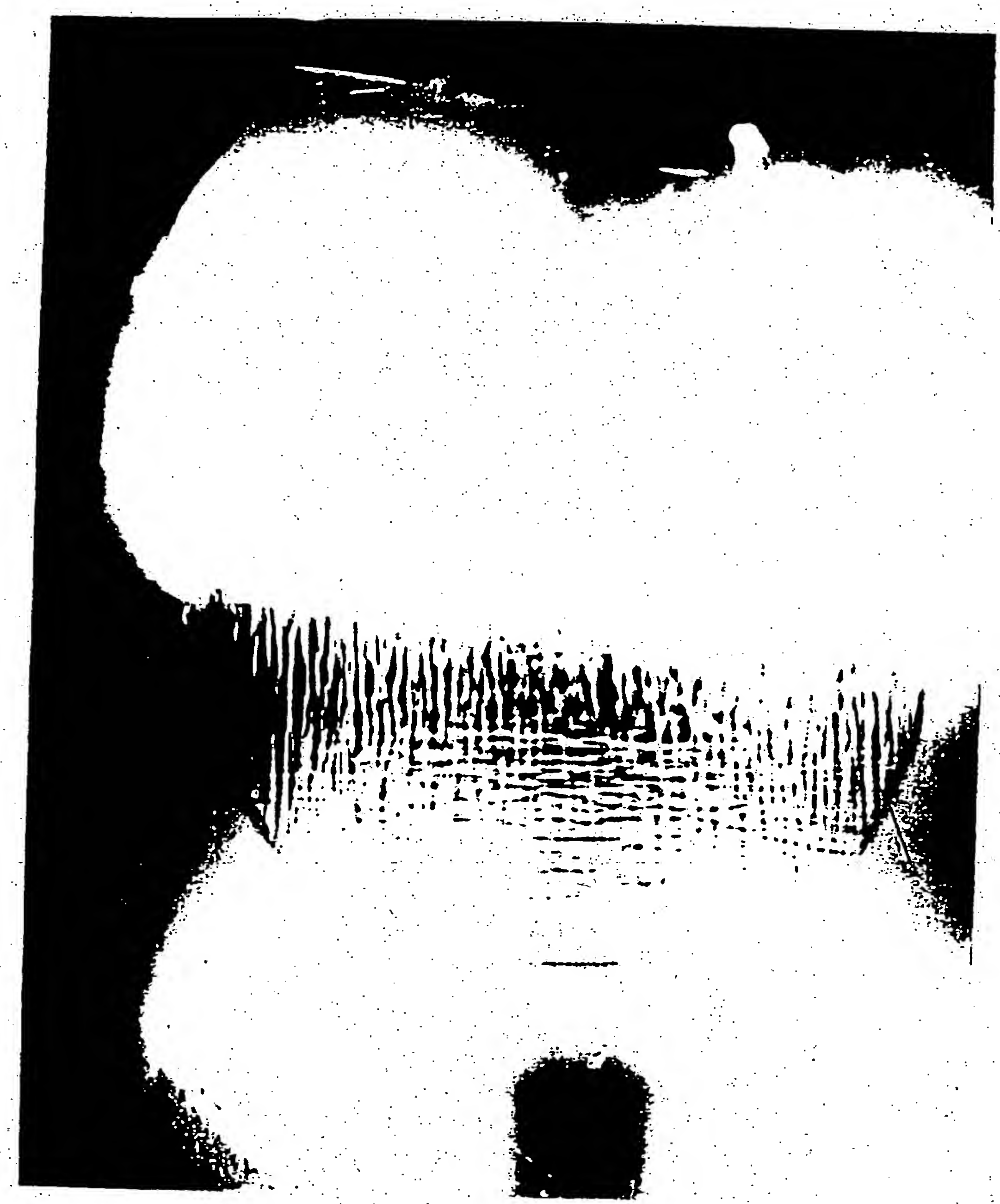

FIG. 7

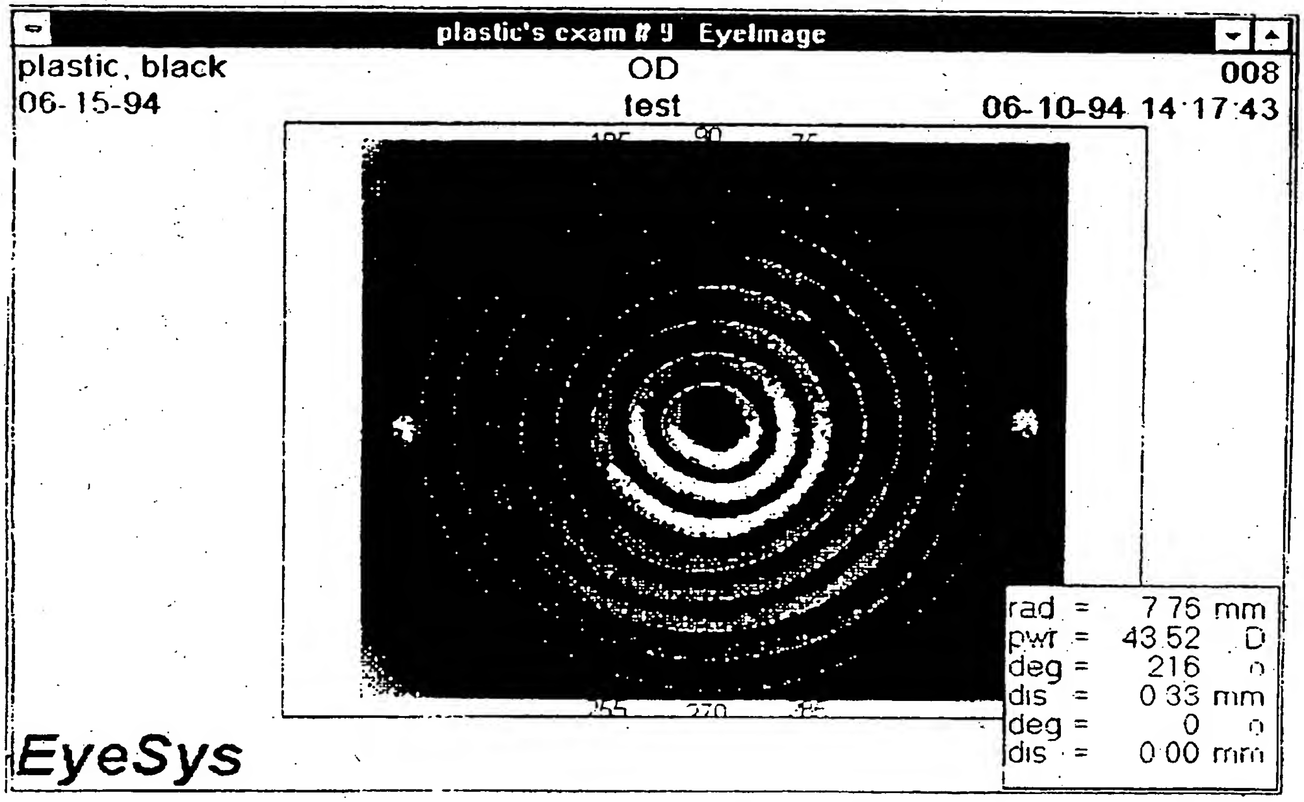
plastic's exam # 9 EyeImage
plastic, black
OD
008
06-15-94
test
06-10-94 14:17:43
90
270
rad = 7.76 mm
pwr = 43.52 D
deg = 216 °
dis = 0.33 mm
deg = 0 °
dis = 0.00 mm
EyeSys

FIG.8

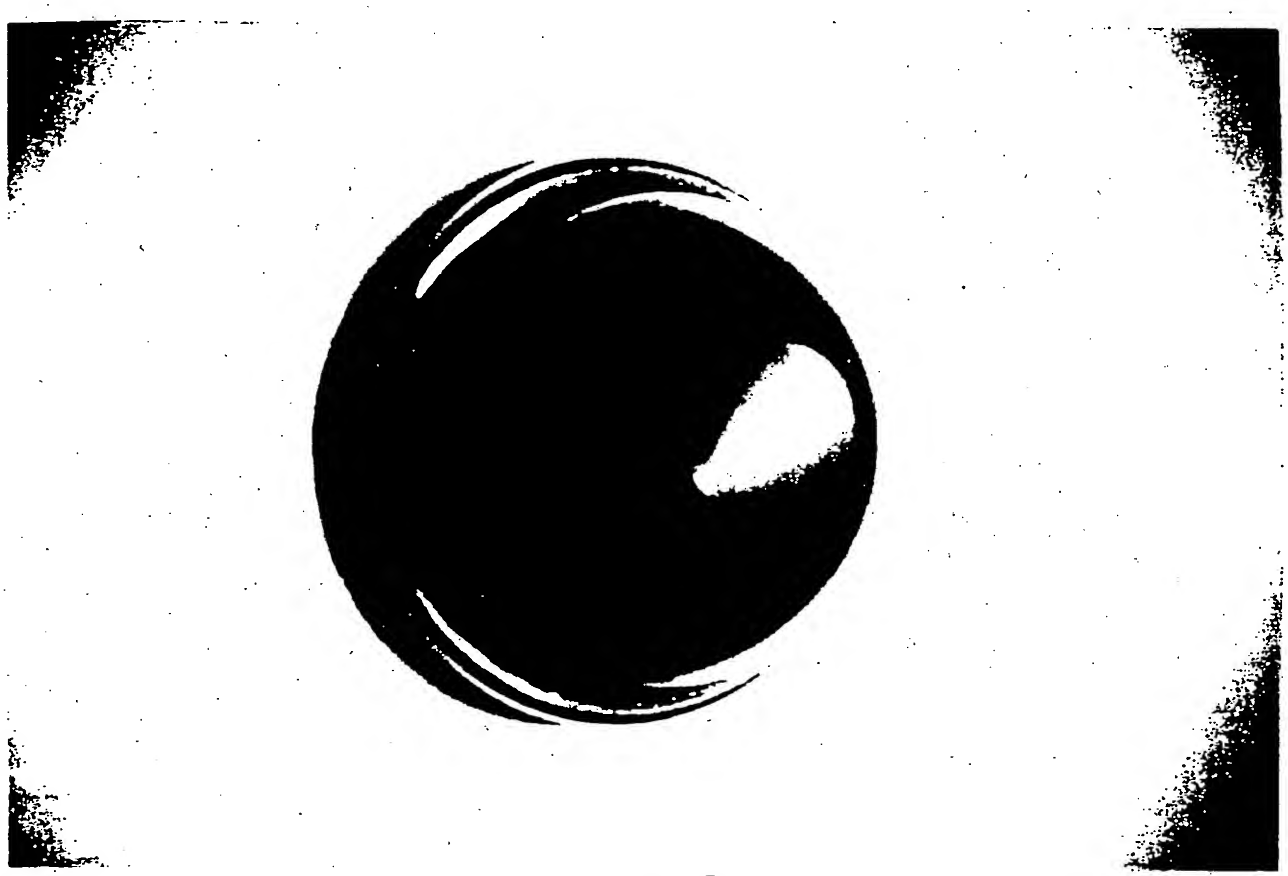

FIG.9

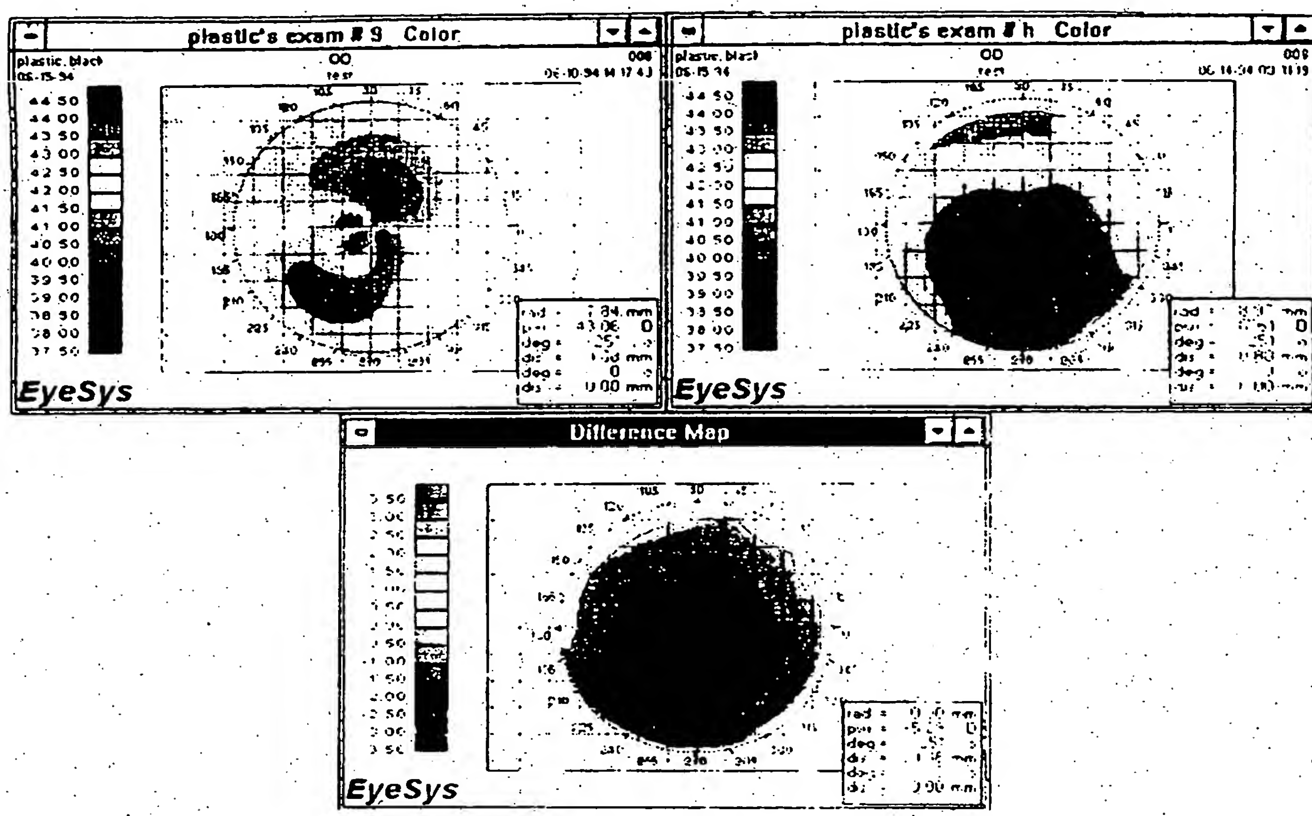
plastic's exam # 9 Color
plastic's exam # h Color
Difference Map
EyeSys
EyeSys
EyeSys

FIG.10

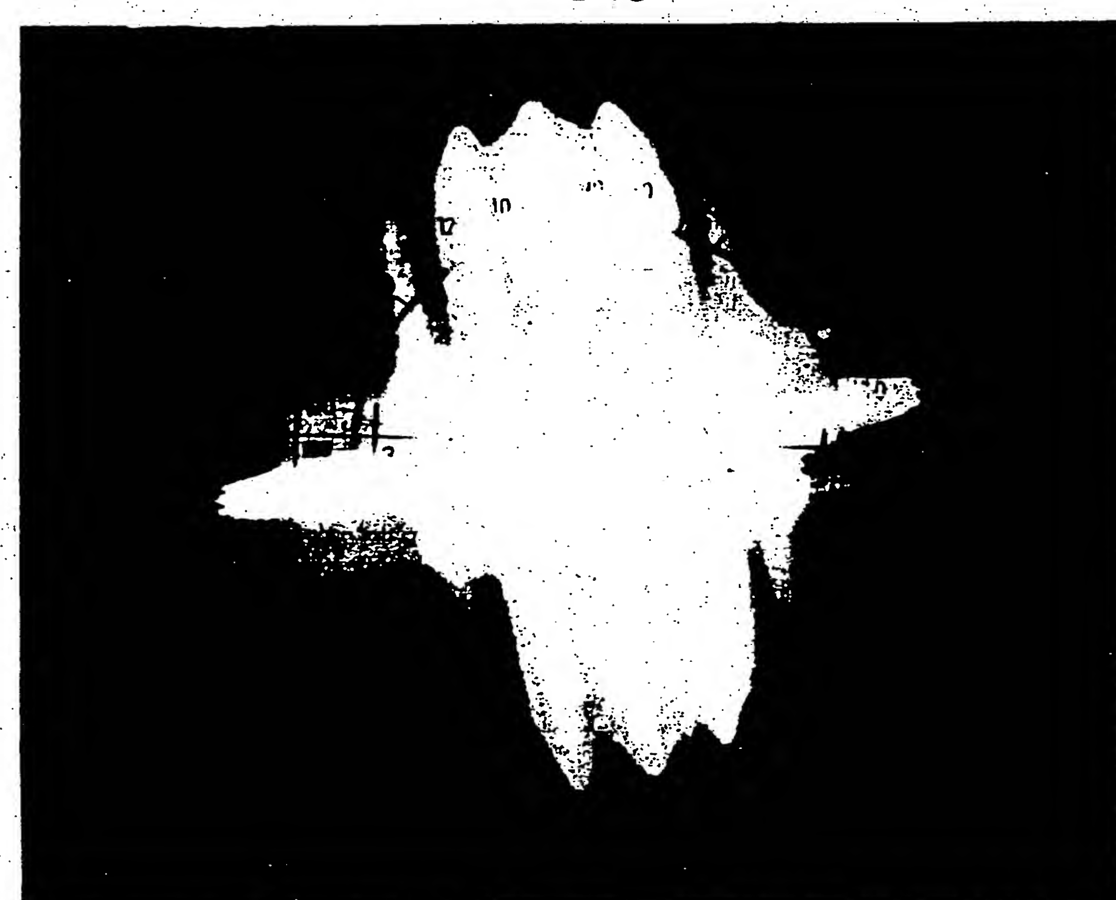

FIG.12

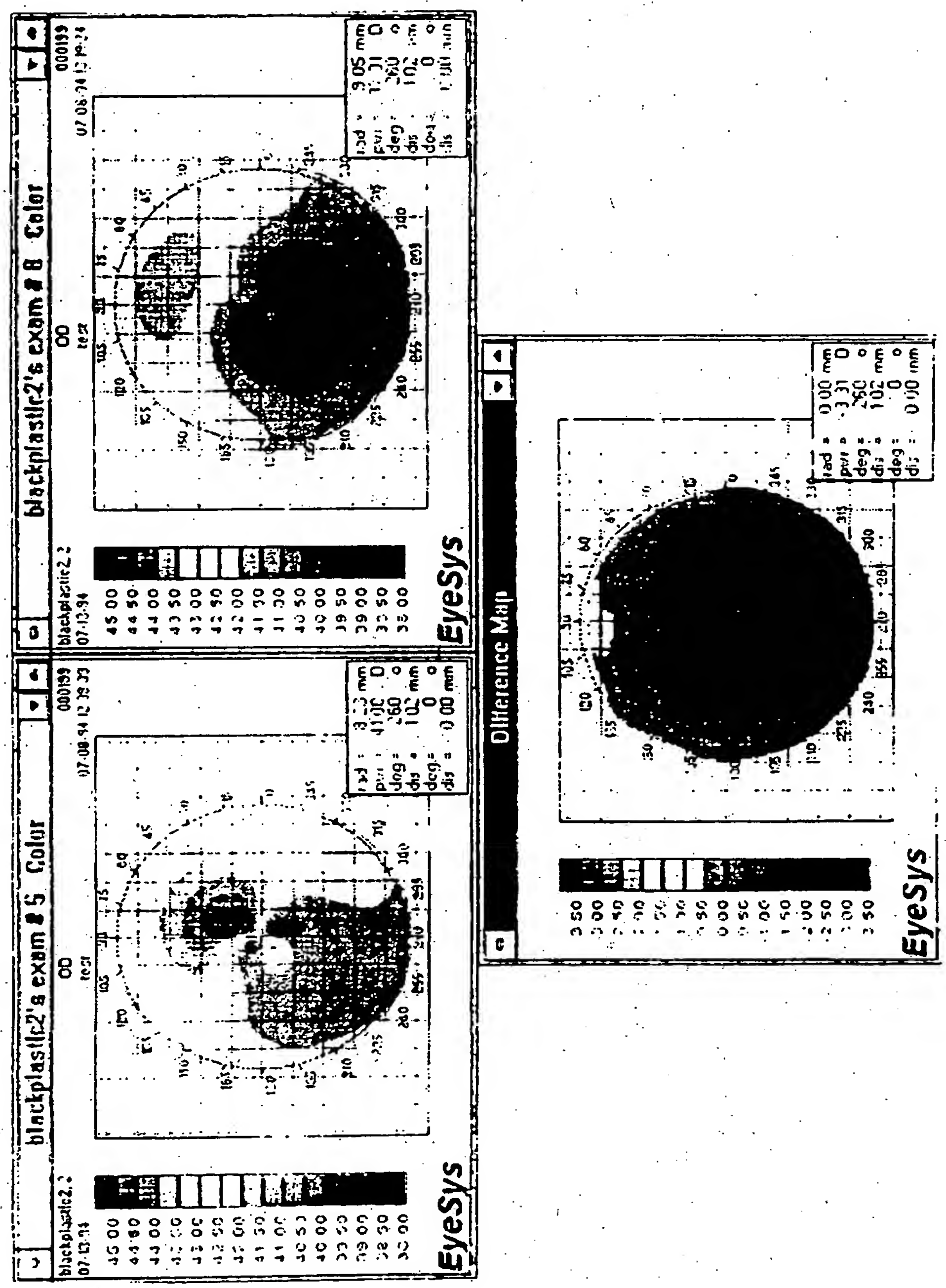
blackplastic2's exam # 5 Color
blackplastic2's exam # 8 Color
Difference Map
EyeSys
EyeSys
EyeSys

FIG.11

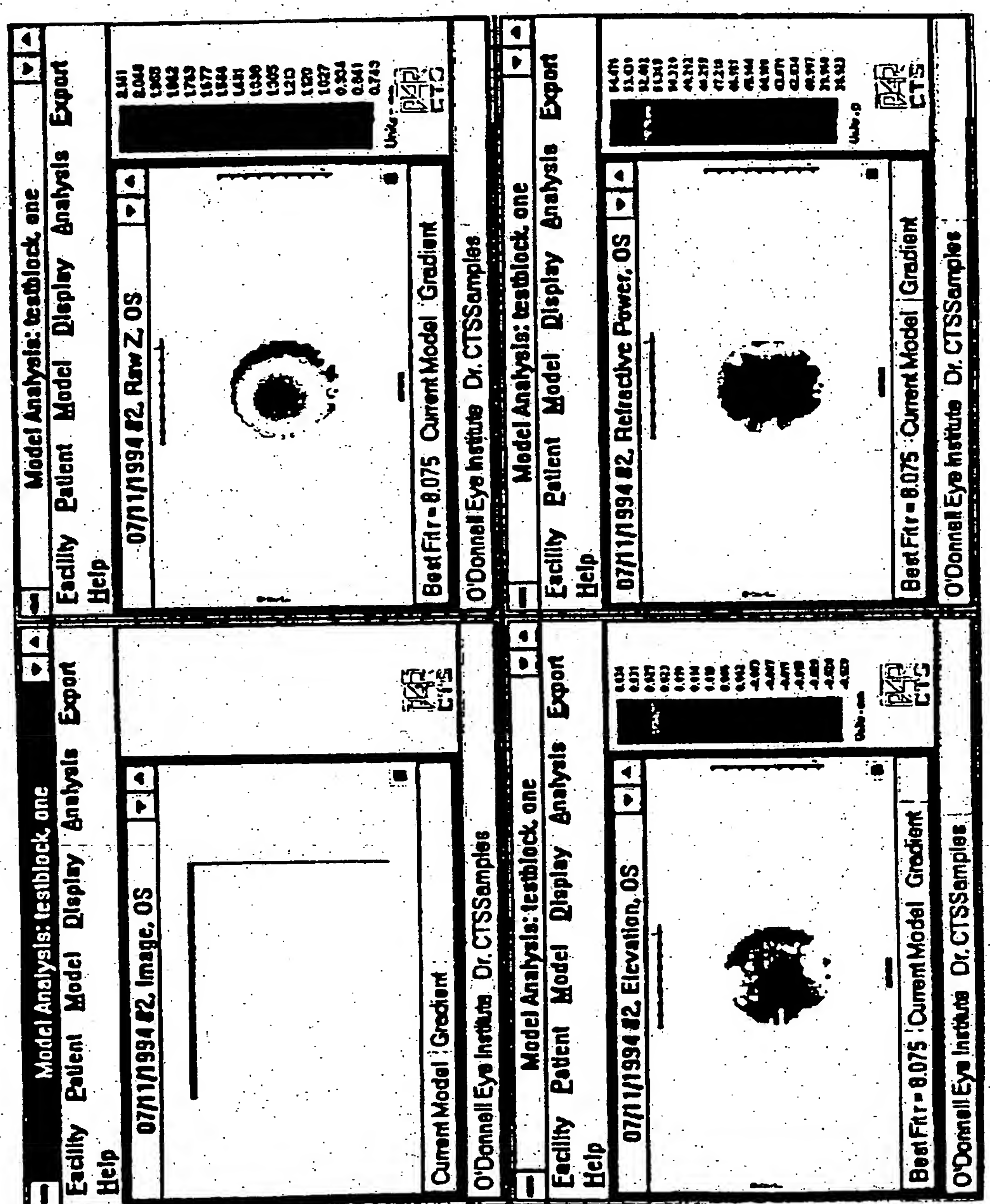
Model Analysis: testblock. one
Facility Patient Model Display Analysis Export
Help
07/11/1994 #2, Image, OS
Current Model : Gradient
O'Donnell Eye Institute Dr. CTSSamples
Model Analysis: testblock. one
Facility Patient Model Display Analysis Export
Help
07/11/1994 #2, Raw Z, OS
Best Fit r = 8.075 Current Model Gradient
O'Donnell Eye Institute Dr. CTSSamples
Model Analysis: testblock. one
Facility Patient Model Display Analysis Export
Help
07/11/1994 #2, Elevation, OS
Best Fit r = 8.075 Current Model Gradient
O'Donnell Eye Institute Dr. CTSSamples
Model Analysis: testblock. one
Facility Patient Model Display Analysis Export
Help
07/11/1994 #2, Refractive Power, OS
Best Fit r = 8.075 Current Model Gradient
O'Donnell Eye Institute Dr. CTSSamples
CTS

FIG. 14

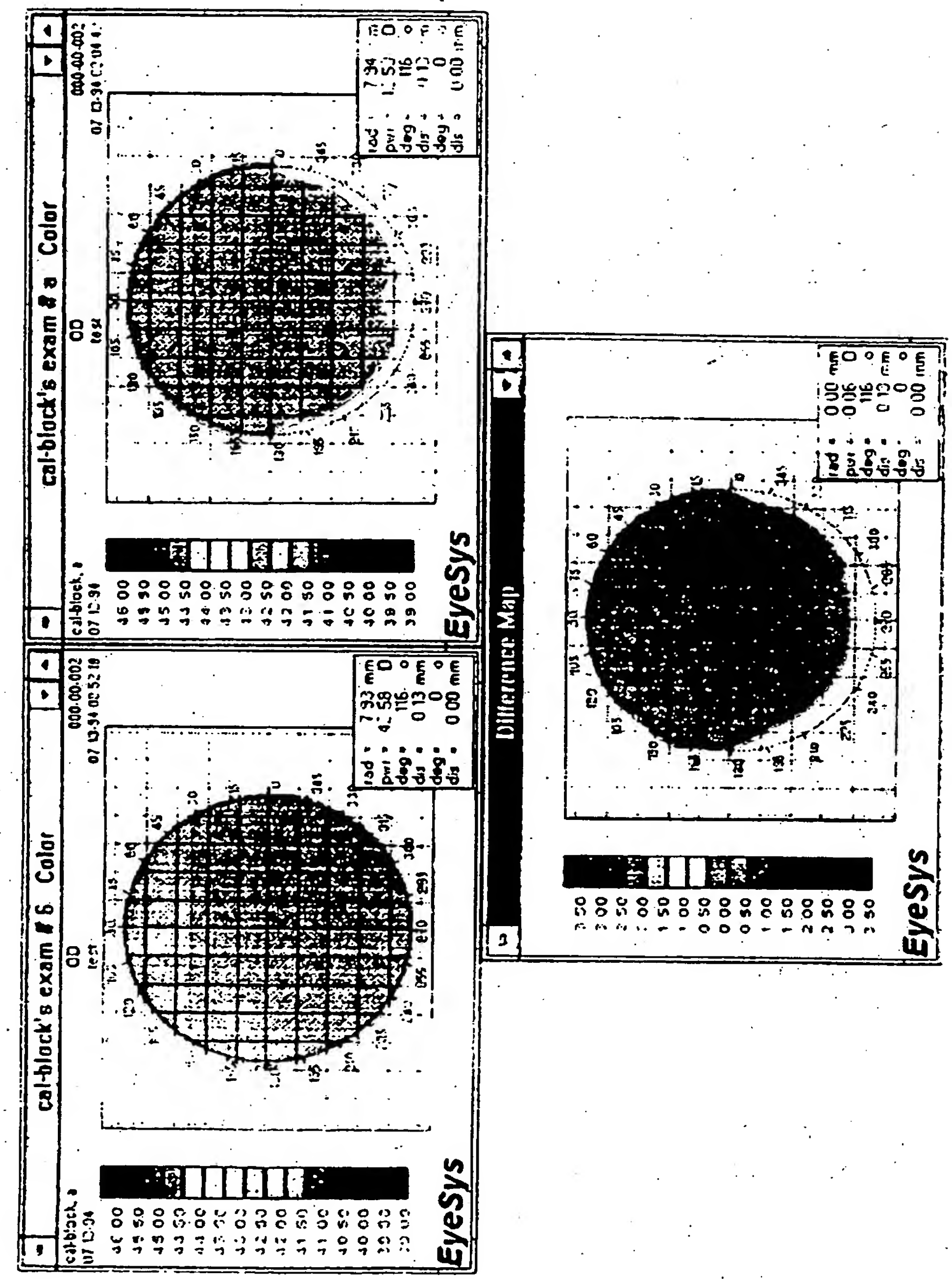
cal-block's exam # a Color
OD
EyeSys
cal-block's exam # 6 Color
OD
EyeSys
Difference Map
EyeSys

FIG.15

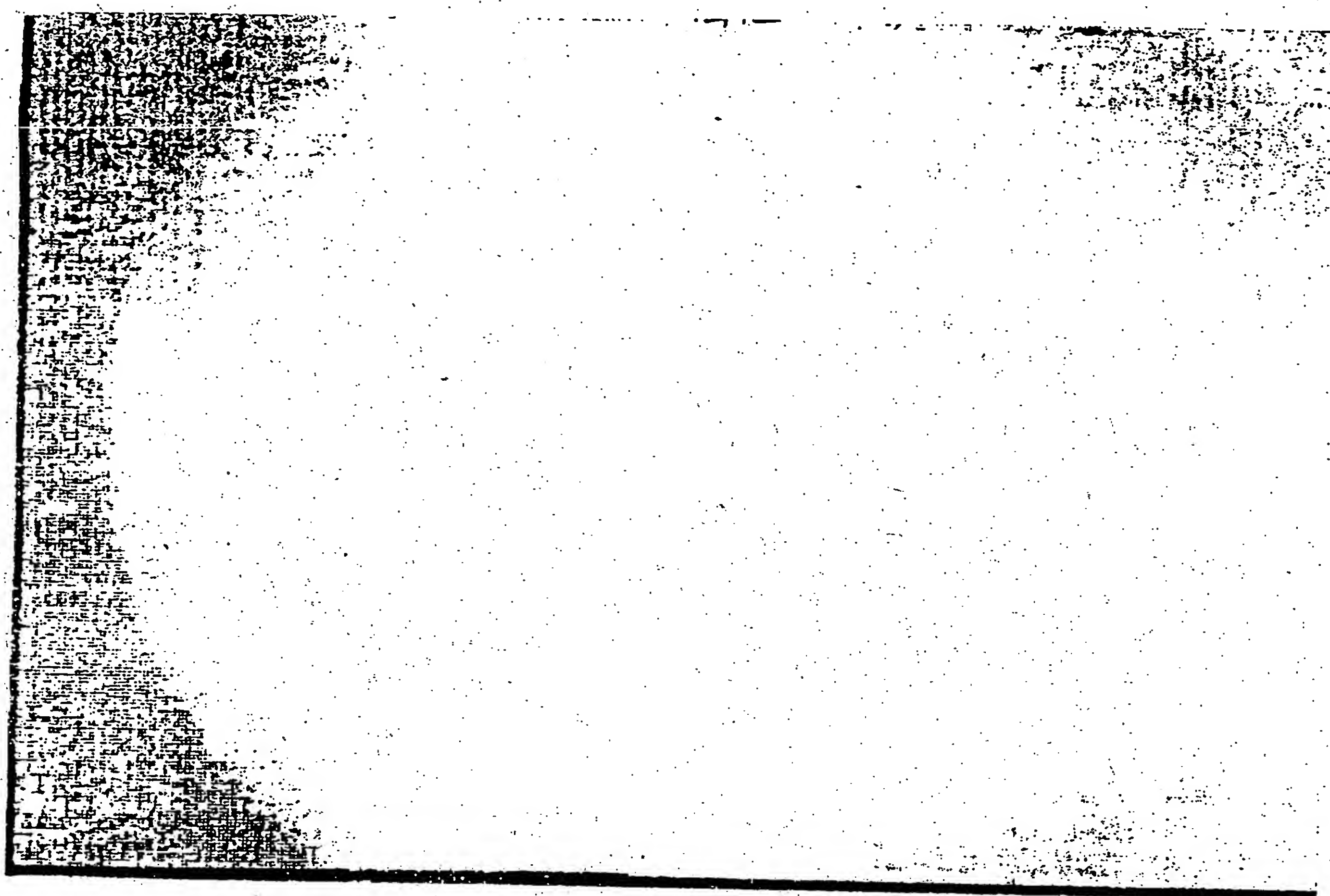

FIG. 16

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/03800

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/00
US CL :606/5, 10, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/2, 3-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,163,934 (MUNNERLYN) 17 November 1992, see column 3 line 55 to column 4 line 2.	2, 6 --- 1, 3-5, 7-10
Y	US, A, 4,669,466 (L'ESPERANCE) 02 June 1987, see the entire document.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 MAY 1996	25 JUL 1996

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